

## Food and Drug Administration, HHS

## § 520.1628

(2) *Cats*—(i) *Amount*—(A) One 11.4-mg tablet, as needed, for use as in paragraph (d)(2)(ii)(A) of this section.

(B) One 11.4-mg tablet, once or twice weekly, for use as in paragraph (d)(2)(ii)(B) of this section.

(ii) *Indications for use*—(A) For the treatment of flea infestations on cats and kittens 4 weeks of age and older and 2 lbs of body weight or greater.

(B) The concurrent use of nitenpyram tablets as in paragraph (d)(2)(i)(B) of this section with flavored lufenuron tablets as in § 520.1288(c)(2) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

[68 FR 51906, Aug. 29, 2003]

### § 520.1615 Omeprazole.

(a) *Specifications*. Each gram of paste contains 0.37 gram omeprazole.

(b) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Special considerations*. When labeled for use as in paragraph (d)(2)(i) of this section, product labeling shall bear: “Federal law restricts this drug to use by or on the order of a licensed veterinarian.”

(d) *Conditions of use in horses*—(1) *Amount*—(i) For treatment of gastric ulcers, 1.8 milligrams per pound (mg/lb) of body weight (4 milligrams per kilogram (mg/kg)) once daily for 4 weeks. For prevention of recurrence of gastric ulcers, 0.9 mg/lb of body weight (2 mg/kg) once daily for at least an additional 4 weeks.

(ii) For prevention of gastric ulcers using the premarked syringe, one dose per day for up to 28 days. Each dose delivers at least 1 mg/kg of body weight. Horses over 1,200 lb body weight should receive two doses per day.

(2) *Indications for use*. (i) For treatment and prevention of recurrence of gastric ulcers in horses and foals 4 weeks of age and older.

(ii) For prevention of gastric ulcers in horses.

(3) *Limitations*. Do not use in horses intended for human consumption.

[69 FR 13220, Mar. 22, 2004]

### § 520.1616 Orbifloxacin tablets.

(a) *Specifications*. Each tablet contains 5.7, 22.7, or 68 milligrams of orbifloxacin.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount*. 2.5 to 7.5 milligrams per kilogram body weight.

(ii) *Indications for use*. For management of diseases associated with bacteria susceptible to orbifloxacin.

(iii) *Limitations*. Administer orally once daily for 2 to 3 days beyond cessation of clinical signs for up to a maximum of 30 days. If no improvement is seen within 5 days, diagnosis should be reevaluated and a different course of therapy considered. Orbifloxacin is contraindicated in immature dogs and cats during the rapid growth phase. Orbifloxacin and other quinolones have been shown to cause arthropathy in immature animals of most species. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[62 FR 29012, May 29, 1997, as amended at 62 FR 61627, Nov. 19, 1997]

### § 520.1628 Oxfendazole powder and pellets.

(a) *Specifications*—(1) *Powder for suspension*. Each gram of powder contains 7.57 percent oxfendazole.

(2) *Pellets*. Each gram of pellets contains 6.49 percent oxfendazole.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. 10 milligrams per kilogram of body weight.

(2) *Indications for use*. The drug is used in horses for removal of the following gastrointestinal worms: Large roundworms (*Parascaris equorum*), mature and immature pinworms (*Oxyuris equi*), large strongyles (*Strongylus edentatus*, *Strongylus vulgaris*, and *Strongylus equinus*), and small strongyles.

(3) *Limitations*—(i) *Powder for suspension*. For gravity administration via stomach tube or for positive administration via stomach tube and dose syringe. Discard unused portions of suspension after 24 hours. Mix drug according to directions prior to use. Administer drug with caution to sick or debilitated horses. Not for use in horses intended for food. Federal law

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restricts this drug to use by or on the order of a licensed veterinarian.

(ii) *Pellets*. The drug is given by sprinkling on the grain portion of the ration. Withholding feed or water prior to administration is not necessary. Administer drug with caution to sick or debilitated horses. Not for use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[44 FR 35211, June 19, 1979, as amended at 46 FR 26301, May 12, 1981; 46 FR 60570, Dec. 11, 1981; 49 FR 28549, July 13, 1984; 61 FR 5506, Feb. 13, 1996]

### § 520.1629 Oxfendazole paste.

(a)(1) *Specifications*. Each gram of paste contains 0.375 gram oxfendazole (37.5 percent).

(2) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount*. 10 milligrams per kilogram (2.2 pounds) of body weight.

(ii) *Indications for use*. The drug is used in horses for removal of the following gastrointestinal worms: Large roundworms (*Parascaris equorum*), mature and 4th stage larvae pinworms (*Oxyuris equi*), large strongyles (*Strongylus edentatus*, *S. vulgaris*, and *S. equinus*), and small strongyles.

(iii) *Limitations*. Horses maintained on premises where reinfection is likely to occur should be retreated in 6 to 8 weeks. Withholding feed or water prior to use is unnecessary. Administer drug with caution to sick or debilitated horses. Not for use in horses intended for food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(b)(1) *Specifications*. Each gram of paste contains 185 milligrams of oxfendazole (18.5 percent).

(2) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(3) *Related tolerances*. See § 556.495 of this chapter.

(4) *Conditions of use*—(i) *Amount*. 4.5 milligrams per kilogram of body weight (2.05 milligrams per pound).

(ii) *Indications for use*. The drug is used in cattle for the removal and control of the following worms: lungworms (*Dictyocaulus viviparus*—adult, L4); stomach worms: barberpole worms

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(*Haemonchus contortus* and *H. placei*—adult), small stomach worms (*Trichostrongylus axei*—adult), brown stomach worms (*Ostertagia ostertagi*—adult, L4, inhibited L4); intestinal worms; nodular worms (*Oesophagostomum radiatum*—adult), hookworms (*Bunostomum phlebotomum*—adult), small intestinal worms (*Cooperia punctata*, *C. oncophora*, and *C. mcmasteri*—adult, L4); and tapeworms (*Moniezia benedeni*—adult).

(iii) *Limitations*. For use in cattle only. Treatment may be repeated in 4 to 6 weeks. Cattle must not be slaughtered until 11 days after treatment. Do not use in female dairy cattle of breeding age. Consult a veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[49 FR 38250, Sept. 28, 1984, as amended at 58 FR 39443, July 23, 1993; 61 FR 5506, Feb. 13, 1996]

### § 520.1630 Oxfendazole suspension.

(a) *Specifications*. Each milliliter contains 90.6 or 225.0 milligrams oxfendazole (9.06 or 22.5 percent).

(b) *Sponsor*. See 000856 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.495 of this chapter.

(d) *Conditions of use*—(1) *Horses* (9.06 percent suspension only).

(i) *Amount*. 10 milligrams per kilogram (2.2 pounds) of body weight.

(ii) *Indications for use*. For removal of large roundworms (*Parascaris equorum*), mature and 4th stage larvae pinworms (*Oxyuris equi*), large strongyles (*Strongylus edentatus*, *S. vulgaris*, and *S. equinus*), and small strongyles.

(iii) *Limitations*. Administer 9.06 percent suspension by stomach tube or dose syringe. Horses maintained on premises where reinfection is likely to occur should be retreated in 6 to 8 weeks. Withholding feed or water prior to use is unnecessary. Administer drug with caution to sick or debilitated horses. Do not use in horses intended for food. If administered by stomach tube: Federal law restricts this drug to use by or on the order of a licensed veterinarian. If administered by dose syringe only: Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.